

The opinion in support of the decision being entered today was not written
for publication and is not binding precedent of the Board:

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte DOUGLAS T. ROSS,
HANSJÖRG SAUER,
GREGORY S. HAMILTON, and
JOSEPH P. STEINER

Appeal No. 2003-0911
Application No. 09/134,472

REMAND TO THE EXAMINER

Before WINTERS, ADAMS, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

ON REMAND TO THE EXAMINER

On consideration of the record, we find that this case is not ready for a
disposition on appeal. Accordingly, we remand the application to the examiner for
further proceedings not inconsistent with the views expressed herein.

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U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

The Record

In their Appeal Brief, applicants presume that Teri et al.¹ constitutes evidence of record. See Paper No. 18, page 7. That, however, is not clear.

On September 13, 2001, the PTO received applicants' Notice of Appeal from the examiner's decision finally rejecting claims 1 through 4, 6 through 11, and 23 through 38, which are all the claims pending in this application. In a separate paper received on the same date, captioned "Response and Amendment," applicants proffered an amendment to claim 1 and submitted remarks (Paper No. 15). Applicants argued that the examiner should "reconsider and withdraw" the rejections of their claims in light of the amendment and remarks (id. at page 17). Further, applicants enclosed a copy of the Teri reference with their "Response and Amendment" and referred to Teri in their remarks (id. at pages 9 and 15).

In an Advisory Action mailed October 19, 2001 (Paper No. 16), the examiner denied entry of applicants' proffered amendment. The examiner indicated that applicants' remarks have been considered but do not place the application in condition for allowance for "the reasons of record." The examiner did not specifically comment on the Teri reference, or expressly state whether that reference was admitted and made of record. See 37 CFR § 1.195 ("Affidavits, declarations, or exhibits submitted

¹ Teri et al. (Teri), "Imipramine in the Treatment of Depressed Alzheimer's Patients: Impact on Cognition," The Journals of Gerontology, Vol. 46, No. 6, pp. 372-377 (November 1991)

after the case has been appealed will not be admitted without a showing of good and sufficient reasons why there were not earlier presented").

On return of this application to the Examining Corps, we recommend that the examiner (1) take into account the provisions of 37 CFR § 1.195, and (2) expressly state whether the Teri reference has been admitted and made of record. Based on our review of the file, it would not appear that applicants presented "a showing of good and sufficient reasons" why that reference, and the arguments based thereon, were not earlier presented. Again, applicants refer to Teri in their Appeal Brief, and it is important that we know whether this reference is, or is not, of record.

Claim 6

On its face, dependent claim 6 would not appear to comply with the provisions of 35 U.S.C. § 112, fourth paragraph. This follows because independent claim 1 is restricted to a method for treating a nerve-related vision disorder or treating memory impairment in a mammal in need thereof. In other words, the "mammal in need thereof" in claim 1 suffers from a specified disorder. On the contrary, the method of claim 6 "is for improving naturally-occurring vision in an animal, in the absence of any ophthalmologic disorder, disease, or injury." On these facts, it would not appear that dependent claim 6 specifies a further limitation of the subject matter claimed in claim 1; or that claim 6 may be construed to incorporate by reference all the limitations of claim 1. See 35 U.S.C. § 112, fourth paragraph.

On return of this application to the Examining Corps, we recommend that the examiner review dependent claim 6 for compliance with the provisions of 35 U.S.C. § 112, fourth paragraph.

The Scope of Claim 1

With the exception of dependent claim 6, all of the claims stand or fall together for the purposes of this appeal. ("The claims are presented in two groups. The first group consists of claims 1-4, 7-11, and 23-38. The second group consists of claim 6." Paper No. 18, section VII.) We therefore focus attention on independent claim 1, the broadest claim on appeal. See 37 CFR § 1.192(c)(7).

Claim 1 is drawn to a method for treating a nerve-related vision disorder or treating memory impairment in a mammal in need thereof by administering to said mammal an effective amount of a specified N-heterocyclic ring compound. The compound must contain "a carboxylic acid or carboxylic acid isostere moiety thereof" attached to the 2-carbon of the N-heterocyclic ring. The claim specifies that, when treating a nerve-related vision disorder, the disorder is selected from the group consisting of specified impairments, disorders, diseases, and injuries. It is important to note, however, that claim 1 does not require treating a nerve-related vision disorder. The claim embraces, inter alia, a method for treating "memory impairment" in a mammal in need thereof.

During patent examination, the pending claims must be interpreted as broadly as their terms reasonably allow. In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320,

1322 (Fed. Cir. 1989). As stated in In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983):

It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification, In re Prater, 415 F.2d 1393, 1404, 162 USPQ 541, 550 (CCPA 1969), and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art. In re Johnson, 558 F.2d 1008, 1016, 194 USPQ 187, 194 (CCPA 1977).

With those principles in mind, we turn to applicants' discussion of "memory impairment" in the specification, page 30, line 17 through page 31, line 7. Applicants state that "[m]emory impairment' refers to a diminished mental registration, retention or recall of past experiences, knowledge, ideas, sensations, thoughts or impressions;" and that "[e]xamples of memory impairment include, without limitation, benign forgetfulness . . . and any disorder in which memory deficiency is present" (emphasis added).

On these facts, we conclude that a method for treating "memory impairment" in a mammal in need thereof is not limited to improving cognitive function, retention, or recall. Rather, claim 1 embraces a method for treating "any disorder in which memory deficiency is present" in a mammal. We observe here that Alzheimer's disease is a mental disorder of the elderly manifested by loss of memory and judgement, often accompanied by confusion. See Merriam-Webster's Collegiate Dictionary, Deluxe Edition, published by Merriam-Webster, Inc., Springfield, Mass., page 53 (1998), copy enclosed with this opinion. (Alzheimer's disease . . . a degenerative disease of the central nervous system characterized especially by premature senile mental deterioration).

Following established principles of claim interpretation, we therefore conclude that claim 1 “reads on” a method for treating Alzheimer’s disease in a mammal in need thereof. Our conclusion is reinforced by a perusal of the file wrapper, reflecting that applicants proffered an amendment attempting exclude Alzheimer’s disease from the scope of claim 1 (Paper No. 15). The examiner denied entry of that proposed amendment (Paper No. 16).

On return of this application to the Examining Corps, we recommend that the examiner re-evaluate the rationale set forth in rejecting applicants’ claims under the judicially created doctrine of obviousness-type double patenting over claim 8 of Hamilton ‘537.² In this regard, we note the examiner’s statement that “the claims of the instant application differ [from claim 8 of Hamilton ‘537] only through the claim language of treating vision disorders” (Paper No. 19, page 5, lines 6 and 7). Again, we point out that claim 1 does not require treating a nerve-related vision disorder.³ Rather, claim 1 “reads on” a method for treating Alzheimer’s disease in a mammal in need thereof. It would thus appear that the relationship between appealed claim 1 and the claims of Hamilton ‘537 is closer than indicated by the examiner. It would appear that

² U.S. Patent No. 6,331,537 issued to Hamilton et al. (Hamilton ‘537) on December 18, 2001.

³ Likewise, dependent claim 24 does not require treating a nerve-related vision disorder. That claim depends from claim 1 and recites “wherein the nerve-related vision disorder is retinal ischemia.” In other words, claim 24 embraces a method for treating retinal ischemia or treating memory impairment in a mammal in need thereof. There is no intervening claim, *i.e.*, intervening between claims 1 and 24, which limits the claimed subject matter to a method for treating a nerve-related vision disorder.

Based on our review of applicants’ claims, as presently drafted, no claim is restricted to a method for treating a nerve-related disorder.

appealed claim 1 covers a method for treating Alzheimer's disease in a mammal in need thereof by administering to the mammal the same amount of a compound or compounds meeting terms recited in the method claims of Hamilton '537 drawn to treating a neurological disorder, where the neurological disorder is Alzheimer's disease. Note particularly claims 11 and 14 of Hamilton '537. Under these circumstances, it would appear that a Terminal Disclaimer is required to prevent undue timewise extension of monopoly. See In re Vogel, 422 F.2d 438, 442, 164 USPQ 619, 623 (CCPA 1970) (Appealed claim 10, by reciting "meat," includes pork; its allowance for a full term would extend the time of monopoly of the patented pork process).

The Issue of Structural Obviousness

One further matter warrants attention. In rejecting applicants' claims for obviousness under 35 U.S.C. § 103, and for obviousness-type double patenting, the examiner relies on Hamilton '357.⁴ These rejections, however, have not been adequately briefed in Paper Nos. 18 and 19.

As previously indicated, claim 1 is not restricted to a method for treating a nerve-related vision disorder. Claim 1 recites, in the alternative, a method for treating memory impairment in a mammal in need thereof. It follows, for reasons already discussed, that claim 1 "reads on" a method for treating Alzheimer's disease in a mammal in need thereof. Therefore, respecting the obviousness and obviousness-type

⁴ U.S. Patent No. 6,140,357 issued to Hamilton et al. (Hamilton '357) on October 31, 2000.

double patenting rejections based on Hamilton '357, the examiner and applicants should focus more attention on passages in the prior art pertaining to a method for treating Alzheimer's disease. Note particularly the following passages in Hamilton '357: column 2, lines 39 through 51; column 4, lines 47 through 52; column 11, line 62 through column 12, line 5; and column 25, lines 57 and 58 (i.e., claim 5).

Further, the examiner argues that applicants' recitation of "an N-heterocyclic ring compound containing a . . . carboxylic acid isostere moiety . . . attached to the 2-carbon of the N-heterocyclic ring" does not patentably distinguish over compounds disclosed by Hamilton '357 in a method for treating a neurological disorder, e.g., Alzheimer's disease. In setting forth that argument, the examiner states that "[a]n isostere is a compound resulting from the exchange of an atom or a group of atoms with another, broadly similar, atom or group of atoms" (Paper No. 19, page 8, lines 1 and 2). The examiner, however, does not provide evidentiary basis for, or otherwise support, that definition of "isostere." Furthermore, applicants provide a gloss on the meaning of the term "isostere" in their specification, page 26, line 12 through page 28, line 20. It is not clear whether the examiner has interpreted the claim language "carboxylic acid isostere moiety" in light of the specification. See In re Sneed, 710 F.2d at 1548, 218 USPQ at 388 (claims should be given their broadest reasonable interpretation consistent with the specification, and claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art); In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971) (definiteness of claim language must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular

application disclosure as it would be interpreted by a person having ordinary skill in the art).

For their part, applicants argue that:

[T]he substituent attached to the 2-position of the '357 patent compounds is required to be an ester or amide, which is in turn required to be further substituted. In contrast, in the compounds of the present invention, the substituent attached to the 2-position is (1) not permitted be [sic] either an ester or amide and (2) is not permitted to be further substituted. [Paper No. 18, page 4, second paragraph]

That argument, however, appears inconsistent with the instant specification and claims.

For example, see page 25 of the Appeal Brief (Paper No. 18), last compound illustrated, which has an unsubstituted amide group attached at the 2-position of the heterocyclic ring. We also observe that applicants contemplate carboxylic acid isosteres attached at the 2-carbon of the N-heterocyclic ring such as, e.g., -CON(R³)₂. See applicants' specification, page 26, line 21. Those isosteres would not appear to patentably distinguish over the compounds described by Hamilton '357 where Y is NR₂; R₂ is C₁-C₆ alkyl; and Z is straight or branched chain alkyl. See Hamilton '357, column 25, claim 2.

On return of this application to the Examining Corps, we recommend that the examiner take the above comments into account in re-evaluating the rejection of applicants' claims for obviousness under 35 U.S.C. § 103, and for obviousness-type double patenting over Hamilton '357. We also recommend that applicants re-evaluate

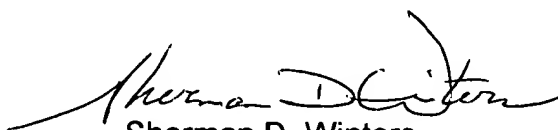
their argument in Paper No. 18, page 4, second paragraph, which appears inconsistent with the instant specification and claims.

Conclusion

In conclusion, for the reasons set forth in the body of this opinion, we find that this case is not ready for a disposition on appeal. Accordingly, we remand the application to the examiner for further proceedings not inconsistent with the views expressed herein.

This application, by virtue of its "special" status, requires an immediate action. Manual of Patent Examining Procedure § 708.01 (8th ed., rev. 1, February 2003). It is important that the Board be informed promptly of any action affecting the appeal in this case.


REMANDED



Sherman D. Winters
Administrative Patent Judge



Donald E. Adams
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge

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Appeal No. 2003-0911
Application No. 09/134,472

Page 11

Guilford Pharmaceuticals Co.
Foley & Lardner
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Washington, DC 20007-5143

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Merriam-Webster's Collegiate[®] Dictionary

DELUXE EDITION



Merriam-Webster, Incorporated
Springfield, Massachusetts



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altruist

— **al-tru-ist** \trū-ist\ *noun*
— **al-tru-is-tic** \al-trū-'is-tik\ *adjective*
— **al-tru-is-ti-cal-ly** \-ti-k(ə-)lē\ *adverb*
al-u-lā \al-yə-lə\ *noun, plural -lāe* \-lē, -lī\ [New Latin, from Latin, diminutive of *ala* wing — more at **AISLE**] (1772)
: the process of a bird's wing corresponding to the thumb and bearing a few short quills — called also *bastard wing*
'al-um \a-ləm\ *noun* [Middle English, from Middle French *alum*, *alun*, from Latin *alumen*] (14th century)
1 : a potassium aluminum sulfate $KAl(SO_4)_2 \cdot 12H_2O$ or an ammonium aluminum sulfate, $NH_4Al(SO_4)_2 \cdot 12H_2O$ used especially as an emetic and as an astringent and styptic
2 : any of various double salts isomorphous with potassium aluminum sulfate
3 : ALUMINUM SULFATE
al-um \a-ləm\ *noun* [by shortening] (1930)
: ALUMINUS, ALUMINA
al-u-mi-na \a-lū-mə-nə\ *noun* [New Latin, from Latin *alumin-*, *alumen* alum] (1801)
: aluminum oxide Al_2O_3 occurring native as corundum; and in hydrated forms (as in bauxite)
al-u-mi-nate \-nət\ *noun* (1841)
: a compound of alumina with a metallic oxide
al-u-mi-ni-um \al-yə-'mi-nē-əm\ *noun* [New Latin, from *alumina*] (1812)
chiefly British : ALUMINUM
al-u-mi-nize \-lū-mə-'nīz\ *transitive verb*
-nized; -nizing (1934)
: to treat or coat with aluminum
al-u-mi-no-sil-i-cate \a-lū-mə-nō-'si-lə-kāt, -'si-lī-kāt\ *noun* [Latin *alumin-*, *alumen* + *-o-* + International Scientific Vocabulary *silicate*] (1907)
: a combined silicate and aluminate
al-u-mi-nous \a-lū-mə-nəs\ *adjective* (15th century)
: of, relating to, or containing alum or aluminum
al-u-mi-num \a-lū-mə-nəm\ *noun, often attributive* [New Latin, from *alumina*] (1812)
: a bluish-silver-white malleable ductile light trivalent metallic element that has good electrical and thermal conductivity, high reflectivity, and resistance to oxidation and is the most abundant metal in the earth's crust where it always occurs in combination — see **ELEMENT** table
aluminum sulfate *noun* (1873)
: a white salt $Al_2(SO_4)_3$ usually made by treating bauxite with sulfuric acid and used in making paper, in water purification, and in tanning
alum-na \a-ləm-nə\ *noun, plural -nae* \-(ə-)nē also -nī\ [Latin, feminine of *alumnus*] (1879)
1 : a girl or woman who has attended or has graduated from a particular school, college, or university
2 : a girl or woman who is a former member, employee, contributor, or inmate
alum-nus \a-ləm-nəs\ *noun, plural -ni* \-nī\ [Latin, foster son, pupil, from *alere* to nourish — more at **OLD**] (1645)
1 : one who has attended or has graduated from a particular school, college, or university
2 : one who is a former member, employee, contributor, or inmate
al-um-root \a-ləm-rūt, -rūt\ *noun* (1813)
: any of a genus (*Heuchera*) of North American herbs of the saxifrage family having basal rounded or lobed toothed leaves; especially : one (*H. americana*) of eastern North America
al-u-nite \al-yə-nīt, 'a-lə-\ *noun* [French, from *alun* alum] (1868)
: a mineral that consists of a hydrous potassium aluminum sulfate and occurs in massive form or in rhombohedral crystals
al-ve-o-lar \al-'vē-(ə-)lə\ *adjective* (1799)
1 : of, relating to, resembling, or having alveoli; especially : of, relating to, or consti-

tuting the part of the jaws where the teeth arise, the air-containing cells of the lungs, or glands with secretory cells about a central space
2 : articulated with the tip of the tongue touching or near the teethridge
— **al-ve-o-lar-ly** *adverb*
al-ve-o-late \-lət\ *adjective* (circa 1823)
: pitted like a honeycomb (*alveolate* pollen)
al-ve-o-lus \al-'vē-(ə-)ləs\ *noun, plural -li* \-lī, -(ə-)lē\ [New Latin, from Latin, diminutive of *alveus* cavity, hollow, from *alvus* belly, beehive; akin to Lithuanian *aulys* beehive, Greek *aulos* tube, flute] (circa 1706)
1 : a small cavity or pit; as **a** : a socket for a tooth **b** : an air-containing cell of the lungs **c** : an acinus of a compound gland **d** : a cell or compartment of a honeycomb
2 : TEETHRIDGE
al-way \ol-(ə-)wā\ *adverb* [Middle English *alwey*, *alneway*, from Old English *ealne weg*, literally, all the way, from *ealne* (accusative of *eall* all) + *weg* (accusative) way — more at **WAY**] (14th century)
archaic : ALWAYS
al-ways \ol-wēz, -wəz, -(ə-)wāz also 'ō- \ *adverb* [Middle English *alwayes*, from *alwey*] (14th century)
1 : at all times : INVARIABLY
2 : FOREVER, PERPETUALLY
3 : at any rate : in any event (as a last resort one can always work)
Al-ye-clover \a-ləs-\ *noun* [probably by folk etymology from New Latin *Alysicarpus*, genus name, from Greek *halysis* chain + *karpos* fruit] (1941)
: a low spreading annual Old World legume (*Alysicarpus vaginalis*) used in the southern U.S. as a cover crop and for hay and forage
alys-sum \a-lī-səm\ *noun* [New Latin, from Greek *alysion*, plant believed to cure rabies, from neuter of *alysos* curing rabies, from *a-* + *lyssa* rabies] (1548)
1 : any of a genus (*Alyssum*) of Old World herbs of the mustard family with small usually yellow racemose flowers
2 : SWEET ALYSSUM
Alz-hei-mer's disease \alts-,hī-mərz-, 'alts- \ *noun* [Alois Alzheimer (died 1915) German physician] (1912)
: a degenerative disease of the central nervous system characterized especially by premature senile mental deterioration — called also Alzheimer's \diamond
am [Middle English, from Old English *eom*; akin to Old Norse *em* am, Latin *sum*, Greek *eimi*] present 1st singular of **BE**
AM \ā-,em\ *noun, often attributive* [amplitude modulation] (1940)
: a broadcasting system using amplitude modulation; also : a radio receiver of such a system
ama \ā-(ə-)mä\ *noun, plural amas or ama* [Japanese] (1946)
: a Japanese diver especially for pearls
amah \ā-(ə-)mä\ *noun* [Portuguese *ama* wet nurse, from Medieval Latin *amma*] (1839)
: an Oriental female servant; especially : a Chinese nurse
amain \ə-'mān\ *adverb* (1540)
1 : with all one's might (attacking a huge rack of beef with a cleaver, she flailed away *amain* — Jay Jacobs)
2 *archaic* **a** : at full speed **b** : in great haste
3 *archaic* : to a high degree : EXCEEDINGLY (they whom I favour thrive in wealth *amain* — John Milton)
Ama-le-kite \a-mə-le-'kīt, ə-'ma-lə-'kīt\ *noun* [Hebrew *Āmālēqī*, plural from *Āmālēq* Amalek, grandson of Esau] (1560)
: a member of an ancient nomadic people living south of Canaan
amalgam \ə-'mal-gəm\ *noun* [Middle English *amalgame*, from Middle French, from Medieval Latin *amalgama*] (15th century)
1 : an alloy of mercury with another metal that

is solid or liquid at room temperature according to the proportion of mercury present and is used especially in making tooth cements
2 : a mixture of different elements : COMBINATION
amal-gam-ate \-gə-,māt\ *transitive verb -at-ed; -at-ing* (1617)
: to unite in or as if in an amalgam; especially : to merge into a single body
synonym see **MIX**
— **amal-gam-ator** \-mā-tər\ *noun*
amal-gam-ation \ə-,mal-gə-'mā-shən\ *noun* (1612)
1 **a** : the action or process of amalgamating
: UNITING **b** : the state of being amalgamated
2 : the result of amalgamating : AMALGAM
3 : CONSOLIDATION, MERGER (*amalgamation* of two corporations)
aman-dine \ā-,mān-'dēn\ *adjective* [French] (1945)
: prepared or served with almonds
am-a-ni-ta \a-mə-'nī-tə, -'nē- \ *noun* [New Latin, genus name, from Greek *amanitai*, plural, a kind of fungus] (1899)
: any of a genus (*Amanita*) of white-spored fungi that typically have a volva and an annulus about the stipe and that includes some deadly poisonous forms
am-a-ni-tin \-nī-'tīn, -'nē- \ *noun* [*amanita* + -in] (circa 1847)
: a highly toxic peptide that is produced by the death cap and that selectively inhibits mammalian RNA polymerase
aman-ta-dine \ə-'man-tə-,dēn\ *noun* [International Scientific Vocabulary *amantad-* (alteration of *adamantane*, $C_{10}H_{16}$) + *amine*] (1964)
: a drug used especially as the hydrochloride $C_{10}H_{17}N \cdot HCl$ to prevent infection (as by an influenza virus) by interfering with virus penetration into host cells
aman-u-en-sis \ə-,man-yə-'wen(t)-səs\ *noun, plural -en-ses* \-(ə-)sēz\ [Latin, from (*servus*) a man slave with secretarial duties] (1619)
: one employed to write from dictation or to copy manuscript
am-a-ranth \a-mə-,ran(t)th\ *noun* [Latin *amarantus*, a flower, from Greek *amaranton*, from neuter of *amarantos* unfading, from *a-* + *marainein* to waste away] (1548)



amanita

WORD HISTORY
Alzheimer's disease — Alzheimer's disease is named after the German neurologist Alois Alzheimer (1864–1915). The majority of his medical contributions centered on the structure of nerve tissue. In 1906 he undertook the autopsy of a 55-year-old patient who had died with severe dementia. In examining the brain he noted the abnormal presence of neuritic plaques, structures that had previously been found only in the brains of quite elderly patients. He also noted a neurofibrillary tangle (an abnormal fibrous structure within the neurons) that had not been previously described and whose presence signaled the discovery of a new disease entity. In 1907 Alzheimer published his classic description of premature senile dementia. The disease was later named *Alzheimersche Krankheit* (German for "Alzheimer's disease") by the psychiatrist Emil Kraepelin.

\ə-ləbut \ə-'litten \ər-further \ə-lash \ā-lace
\ā-mop, mar \əu-ot \ch\chin \e-bet \ē-easy
\g-go \i-hit \i-vice \j-job \ŋ-sing \o-go
\ə-law \oi-boy \th\thin \th-the \ū-loot \ū-foot
\y-yet \zh\vision see also Guide to Pronunciation